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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
NELSON, A

ART UNIT	PAPER NUMBER
1638	18

DATE MAILED: 04/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/020,716

Applicant(s)

Rudolf Jung, et al.

Examiner

Amy Nelson

Group Art Unit

1638



X Responsive to communication(s) filed on Mar 15, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) 36-56 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

X Claim(s) 36-56 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None ☐ of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, Paper No(s). 12 & 14

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.

Claim Rejections - 35 USC § 112

2. Claims 36-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record set forth in the Official actions mailed 5/18/99 and 11/22/99, as applied to Claims 6, 7, 14-17, and 21-35. Applicant has provided no arguments in the response filed 3/15/00, and therefore the rejection is maintained.

3. Claims 36-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to transformed cereal plant seed having an elevated lysine, methionine and cysteine content (about 10% to about 35% by weight compared to untransformed cereal plant seed) comprising the modified hordothionin gene of SEQ ID NO:2 (HT12), vectors, plant cells and transformed plants comprising said modified hordothionin gene. The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record set forth in the Official actions mailed 5/18/99 and 11/22/99, as applied to Claims 6, 7, 14-17, and 21-35. Applicant has provided no arguments in the response filed 3/15/00, and therefore the rejection is maintained.

4. Claim 46 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Examiner cannot find support in the as-filed specification for all of the claimed proteins introduced by the amendment filed 3/15/00. Applicant has not specifically pointed to support in the specification for each of the proteins. Therefore, the claimed proteins are believed to constitute new matter. Applicant must identify support for each of the claimed proteins in the specification, or must delete the new matter in response to this Official action.

5. Claims 36-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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At Claim 37, line 1, "the plant" lacks proper antecedent basis. The phrase "a plant" is not recited previously in the instant claim or the parent claim. Appropriate correction is required.

At Claim 37, line 2, the phrase "transgenic protein" is indefinite. It is not clear how a protein is transgenic. Also, it is not clear whether seed is transformed with a gene encoding said protein or with some other gene. Appropriate clarification is required.

At Claim 37, line 2, "elevated level" is unclear because it is not known to what it is compared. It is believed that Applicant intends a modified protein which has an elevated level compared to an unmodified protein.

At Claim 37, lines 2-3, "the preselected amino acid" (singular) lacks proper antecedent basis, and should be changed to --preselected amino acids-- (plural).

At Claim 42, "A seed" (singular) is inconsistent with Claim 56 which recites "seeds" (plural).

At Claim 43, lines 2-3, "compared to a corresponding untransformed cereal plant seed" should be changed to --compared to an endosperm of a corresponding untransformed cereal plant seed--, because the endosperm should be compared with another endosperm, not with a seed.

At Claim 44, line 1, "further comprising" is indefinite. Claim 43 does not recite "comprising," especially with respect to the plant seed, and therefore "further comprising" does not make sense. Appropriate correction is required.

At Claim 46, line 2, "15KD maize protein" is indefinite. In particular "15KD" should be

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--15 kD-- However, there are many different proteins of about 15 kD, so it is unclear what is encompassed by the claim language. Appropriate correction to clarify the metes and bounds of the claimed invention is required.

At Claim 46, line 3, "10 KD maize protein" is indefinite. In particular "10 KD" should be --10 kD--. However, there are many different proteins of about 10 kD, so it is unclear what is encompassed by the claim language. Appropriate correction to clarify the metes and bounds of the claimed invention is required.

At Claim 46, line 4, "is expressed" is indefinite. It is unclear whether the protein is expressed from an endogenous gene or a transgene. Also, it is unclear whether the plant seed is transformed with a gene which encodes said protein, or with another gene. Appropriate clarification is required.

At Claims 47-50, line 2, "in the seed" is inconsistent with parent Claim 43, which recites an elevated amount of preselected amino acids in the endosperm.

At Claims 48-50, lines 1-2, the phrase "the preselected amino acid" is indefinite because it is not clear to which amino acid it refers. It is recommended that the phrase be changed to --each preselected amino acid--.

At Claim 51, line 2, "the content" is indefinite because it is not clear to what it refers, *i.e.* the content where?. It is recommended that at line 3, after "amino acid" --of said polypeptide-- be inserted.

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At Claim 51, line 4, "a corresponding polypeptide" is indefinite. It is believed that Applicant intends a modified polypeptide which has an increased level compared to an unmodified polypeptide

At Claim 52, line 1, "further comprises" is indefinite. Parent Claim 51 does not recite "polypeptide comprises" and hence it is not clear how the polypeptide "further comprises." Appropriate correction is required.

At Claim 53, "seed product" is indefinite. Applicant has not responded to this rejection in the response filed 3/15/00.

At Claim 55, lines 1-2, "the content" is indefinite because it is not clear to what it refers, *i.e.* the content where? It is recommended that at line 2, after "amino acid" --of said polypeptide-- be inserted.

At Claim 55, lines 2-3, "a corresponding untransformed cereal plant seed" is indefinite because it is believed that the polypeptides are compared, not the seeds. Appropriate correction is required.

Claim 56 is unclear because it is believed that the claimed method is directed to increasing the nutritional value of a seeds, not of transformed seeds. It is recommended that the preamble of the claim be amended to recite --A method for producing cereal plant seeds with increased nutritional value comprising--, and that at the end of the claim the following be inserted --wherein the seeds have increased nutritional value as compared to seeds from a corresponding non-transformed cereal plant--.

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At Claim 56, line 2, "seed" (singular) is inconsistent with "seeds" (plural) at lines 1 and 7.

At Claim 56, line 6, "the cereal plant" lacks proper antecedent basis.

Claim Rejections - 35 USC § 102

6. Claims 36-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Falco *et al.* (U.S. Patent 5,773,691). This rejection is repeated for the reasons of record set forth in the Official actions mailed 5/18/99 and 11/22/99. Applicant has provided no arguments in the response filed 3/15/00, and therefore the rejection is maintained.

As discussed in the previous Official actions, Falco discloses transformed maize plants and seeds (including seed grains, meal and feed) with enhanced lysine content and threonine content, obtained by expression of chimeric genes encoding lysine insensitive enzymes or lysine-rich proteins (Abstract; Col. 1, lines 18-65; Col. 6, line 22 - Col. 7, line 44; Col. 9, line 38 - Col. 10, line 37; Col. 30, line 15 - Col. 31, line 62; Examples 22, 23, and 25). In particular, Falco teaches said transformed plants wherein increases in lysine are 10-400% (Col. 6, lines 65-66), and Falco teaches expression cassettes for enhancement of lysine content (Col. 17, line 62 - Col. 20, line 44), particularly which comprise an endosperm-specific promoter, such as the zein promoter (Col. 19, lines 40-55). The maize plants of Falco would necessarily express all endogenous maize proteins, including 15 kD and 10 kD maize proteins. Hence, all of the instant claim limitations have been previously disclosed by Falco.

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Claim Rejections - 35 USC § 103

7. Claims 36-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao *et al.* (U.S. Patent 5,885,802) or Rao *et al.* (U.S. Patent 5,990,389) in view of Rao *et al.* (U.S. Patent 5,885,801) and Applicant's Admission.

The claimed invention is indefinite for the reasons discussed *supra*.

Rao ('802) teaches transformed plants with elevated levels of methionine, a sulfur-containing amino acid, by expression of a mutant barley hordothionin gene with methionine amino acid substitutions (Abstract; Col. 2, line 19 - Col. 3, line 8; Col. 3, line 43-58). Specifically, Rao teaches transformed cereal crops, including maize (Col. 3, lines 55-58), and Rao teaches increased methionine levels of 33% (Col. 2, lines 62-65).

Rao ('389) teaches transformed plants with elevated levels of lysine, by expression of a mutant barley hordothionin gene with lysine amino acid substitutions (Abstract; Col. 1, line 64 - Col. 3, line 26; Col. 3, line 61 - Col. 4, line 50). Specifically, Rao teaches transformed cereal crops, including maize (Col. 4, lines 47-50), and Rao teaches increased lysine levels of 29% (Col. 2, lines 56-58).

Neither Rao ('802) nor Rao ('389) teaches transformed plants comprising elevated levels of another amino acid, and neither teaches specific expression in the endosperm.

Rao ('801) teaches transformed plants with elevated levels of threonine, by expression of a mutant barley hordothionin gene with threonine amino acid substitutions (Abstract; Col. 2, line 20 - Col. 3, line 4; Col. 3, lines 38-52). Specifically, Rao teaches transformed cereal crops, including

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maize (Col. 3, lines 49-52), and Rao teaches increased threonine levels of 29% (Col. 2, lines 60-62)

Applicant admits that endosperm-specific promoters, including the zein promoter and the waxy promoter, were well known in the art at the time of Applicant's invention (Specification, p. 18, lines 7-18).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the invention of Rao ('802) or Rao ('389) to also increase threonine levels as taught by Rao ('801) because that would further enhance the nutritional value of the plants and plant products. Also, it would have been obvious to modify the invention of Rao ('802) or Rao ('389) to direct expression of the hordothionine gene to the endosperm by expressing it behind an endosperm-specific promoter as admitted by Applicant to have been well known in the art. Hordothionine is a seed protein and hence expression in the seed (the major portion of which is endosperm) would be expected to be successful. Also, it was well known in the art that increased nutritional value of seeds was particularly desirable given the importance of grains as a food source in the impoverished regions of the world. One would have had a reasonable expectation of success in view of the success of both Rao ('802) and Rao ('389).

8. Claims 36-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaynes *et al.* (U.S. Patent 5,811,654) in view of Applicant's Admission.

The claimed invention is indefinite for the reasons discussed *supra*.

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Jaynes teaches transformed plants with elevated levels of methionine, lysine and/or threonine by expression of a modified gene with methionine, lysine and/or threonine amino acid substitutions (Abstract; Col. 5, lines 9-14, 29-40; Col. 11, line 24 - Col. 16, line 28; Examples 13-16). Specifically, Jaynes teaches transformed cereal crops, including rice and maize (Col. 6, lines 22-24; Col. 11, lines 35-38; Examples 11 and 12), and seed of the transformed plants (Col. 15, lines 21-23). Jaynes teaches increased amino acid levels of 25-60% (Col. 5, lines 29-33), and Jaynes teaches a modified zein gene (Col. 13, lines 29-32).

Jaynes does not teach specific expression of the modified gene in the endosperm tissue.

Applicant admits that endosperm-specific promoters, including the zein promoter and the waxy promoter, were well known in the art at the time of Applicant's invention (Specification, p. 18, lines 7-18).


It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the invention of Jaynes to direct expression of the modified gene to the endosperm by expressing it behind an endosperm-specific promoter as admitted by Applicant to have been well known in the art. It was well known in the art that increased nutritional value of seeds (the major portion of which is endosperm tissue) was particularly desirable given the importance of grains as a food source in the impoverished regions of the world. One would have had a reasonable expectation of success in view of the success of Jaynes.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**AMY NELSON
PATENT EXAMINER**

Amy J. Nelson, Ph.D.

April 19, 2000